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510(k) Summary

Submitter Information and Date Prepared

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USA

Phone: 410 888 5218
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DEC 2 0 2007

Date Prepared: October 19, 2006

Device Identification

Proprietary Name: MODEL 250 SERIES MATERNAL/FETAL MONITOR
Classification Names: 21 CFR 884.2740 System, Monitoring, Perinatal

Predicate Device Information

Predicate Device	510(k) Number
MODEL 250 SERIES MATERNAL/FETAL MONITOR	K050583

Intended Use Statement

I. Fetal Surveillance

A Corometrics 250 Series Maternal/Fetal Monitoring System is used for non-invasive and invasive monitoring of the fetus during the antepartum period as well as throughout labor and delivery (i.e. fetal heart rate and uterine activity monitoring). Fetal movement detection and fetal heart rate alarm options (user selectable high/low and poor signal quality alarms) are available.

II. Maternal Monitoring

A Corometrics 250 Series Maternal/Fetal Monitoring System is intended for monitoring maternal vital signs to help assess maternal well-being. The vital signs which can be measured with these monitor configurations are summarized as follows:

NOTE: Maternal vital signs provided by the monitor should only be used as an adjunct in patient assessment in conjunction with clinical signs and symptoms.

Blood Pressure: The monitor is intended for use in the non-invasive monitoring of maternal blood pressure (NBP). This monitor is not intended for use in the neonatal or pediatric blood pressure monitoring.

Pulse Oximetry. The monitor is intended for use in the non-invasive monitoring of maternal functional oxygen saturation of arterial hemoglobin (MSpO2).

Heart/Pulse Rate. The monitor is intended for use in the non-invasive monitoring of the maternal heart/pulse rate. Additionally, an MECG waveform 'snapshot" may be displayed and printed.

NOTE: Only the maximum configuration provides both maternal heart rate and pulse rate data.

Device Description

Device Description: The Corometrics 250cx Series Maternal/Fetal Monitoring System consists of the following features/options that can be available in multiple configurations:

- fetal heart rate (via Doppler Ultrasound of FECG)
- maternal uterine activity (via intrauterine pressure catheter or TOCO transducer
- fetal movement detection
- maternal non-invasive blood pressure (clinician prompted or automatic)
- maternal pulse oximetry
- maternal heart/pulse rate (MECG) and ECG waveform "snapshot"
- maternal temperature

Technological Characteristics

The Corometrics 250cx Series Maternal/Fetal Monitor employs the same fundamental scientific technology as the predicate device.

Testing

The subject of this special 510(k) Notification is the design modification of the Model 250 Series Maternal/Fetal Monitor for the addition of color to the primary display, addition of an external display that mimics the primary display, addition of a new serial protocol for central station communications, addition of an external maternal temperature probe, and additional languages in the display.

The maternal temperature probe has been cleared for marketing under the premarket notification K011291. The addition of the probe was included in the verification and validation testing for the modified device.

The Corometrics 250 Series Maternal/Fetal Monitor complies with the voluntary standards as detailed in Tab F of this submission. The following quality assurance measures were applied to the development:

- Risk Analysis
- Requirements specification review
- Design reviews
- Code inspections
- Software and hardware performance testing
- Safety testing
- Environmental testing
- Final validation

Prepared by: AGATA SZYEJA Date 10/19/07

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2007

Ms. Agata Smieja
Global Compliance Leader
GE Healthcare
8880 Gorman RD
LAUREL MD 20723

Re: K072976
Trade/Device Name: Corometrics 250cx Series Monitor
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: December 6, 2007
Received: December 7, 2007

Dear Ms. Smieja:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: MODEL 250cx SERIES MATERNAL/FETAL MONITOR

Indications for Use:

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NOTE: Only the maximum configuration provides both maternal heart rate and pulse rate data.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K012976